

REMARKS

Claims 1-66 are pending in the application. Of these, claims 10, 16, 17, 23, 26-33, 37, 39 and 41-66 have been withdrawn from consideration under a restriction. Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are pending in the application and are rejected.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The antigenic peptide NLVPMVATV of CMV pp65 is disclosed in the application by way of the designation “E495.” *See* Example 16 on page 40 of the specification. The designation is alleged to be an indefinite description of peptide NLVPMVATV and, therefore, is rejected under 35 U.S.C. §112. Applicants respectfully traverse the rejection.

Applicants submit herewith the Declaration of Dr. Richard J. O'Reilly M.D. (“the Declaration”). As discussed by Dr. O'Reilly, a CMV pp65 derived antigenic peptide designated “E495” would be recognized by one of skill in the art to be the peptide NLVPMVATV of CMV pp65, which spans amino acids 495 to 503 of CMV pp65. It is well-known in the art that this peptide has superior antigenicity and, therefore, is the peptide of the CMV pp65₄₉₅ region that is selected for use in applications where such antigenicity is desired (e.g., production of antigen presenting cells). *See* Diamond et al. (1997) Blood, 90:5 pp. 1751-1767 and Solache et al. (1999) J. Immunology, 5512-5518.

Accordingly, applicants reiterate their position that E495 is adequately described in the specification. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Particularly, the Action alleges that the specification fails to show how to make the E495 peptide. Applicants respectfully traverse the rejection.

As discussed above, the Declaration confirms that one of skill in the art would recognize the CMV pp65 E495 peptide of the present invention to be the peptide sequence spanning amino acids 495 to 503 of CMV pp65 (NLVPMVATV), which is described by Diamond et al. (1997) Blood, 90:5 pp. 1751-1767 and Solache et al. (1999) J. Immunology, 5512-5518. Thus, one skilled in the art could simply look to these references to obtain the sequence of the E495 peptide.

The Examiner appears to question whether one skilled in the art would appreciate that the Diamond reference discloses the sequence of E495, as the reference does not expressly refer to the peptide as E495. It is well-established that protein chemists will use shorthand designations for peptides, particularly when a peptide is a segment of a known, sequenced and numbered full protein. A CMV pp65 derived protein named "E495" will instantly be recognized by one of skill in the art to be the segment of pp65 that starts with amino acid number 495 and ending at amino acid number 503 when consulting the Diamond and Solache references.

It is not undue experimentation to refer to an outside reference for the sequence of a known compound. The Wands Factors are not applicable because the peptide is known, its sequence easily accessed, and its use and activity clearly demonstrated. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim Rejections Under 35 U.S.C. §103

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. 103(a) as unpatentable over Latouche, *et al.*, (2000) in view of Boeckh (1999). According to the Action, Latouche teaches an artificial antigen presenting cell comprising a human fibroblast expressing B7.1 and HLA A2.1 (which includes a human B-2 microglobulin) from recombinant viruses and presenting a T-cell specific epitope. The Examiner concludes that the reference teaching differs from the claimed invention only in that it does not teach a CMV antigen.

Boeckh (1999) teaches that CMV causes significant morbidity and mortality after hematopoietic stem cell transplantation.

It is alleged to have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Latouche, *et al.*, (2000) with those of Boeckh (1999) in order to arrive at the claimed invention.

To establish a *prima facie* case of obviousness for the claimed invention, there must have been some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings in the manner proposed by the Examiner. Second, there must have been a reasonable expectation of success at the time the invention was made.

There is no indication that the combination of Latouche with Boeckh provides a reasonable expectation of success in producing the claimed antigen presenting cells. Latouche does not teach or suggest antigen presenting cells for use in combating CMV. Latouche, taken in combination with Boeckh, still fails to show how to modify the teachings of Latouche to arrive at the such cells. Because there is no teaching or suggestion for such modifications, only impermissible hindsight has been used to hunt

through the prior art for the claimed elements. *In re Zurko*, 111 F.3d 887, (Fed. Cir. 1997).

As is the case for the cited references, a combination of references does not render an invention obvious where one skilled in the art would have to vary all parameters or to try each of numerous possible choices until possibly arriving at a successful result, where the references provide either no indication of which parameters are critical or no direction as to which of many choices is likely to be successful. Therefore, at best, the proposed combination is "obvious to try," however, it has long been established that this is not the standard of 35 U.S.C. § 103. *In re Geiger*, 815 F.2d 686, 655 (Fed. Cir. 1987).

Reconsideration and withdrawal of the rejection of claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 under 35 U.S.C. 103(a) is respectfully requested.

Supplemental Information Disclosure Statement

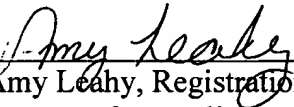
Applicants submit concurrently herewith a Supplemental Information Disclosure Statement for the Examiner's consideration, and respectfully request that the cited references be made of record.

CONCLUSION

Applicants believe that all formalities have been complied with and a complete response has been submitted. It is respectfully submitted that this application is now in condition for allowance with claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40. Should any issues remain or should the Examiner believe that a telephone conference with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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